MAR 1 3 2006

510(k) Summary
Quantum Anterior Cervical Plate System

510(k) Number K060491

Manufacturer Identification

Submitted by: Quantum Orthopedics, Inc.
2744 Loker Ave. W., Suite 100
Carlsbad, CA 92010
760-607-0121

Contact Information: Jason Blain
Chief Technology Officer
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Date Prepared: February 21, 2006

Device Indentification

Proprietary Name: Quantum Anterior Cervical Plate System

Common Name: Spinal Intervertebral Body Fixation Orthosis

Device Classification: 21 CFR 888.3060: Appliance, Fixation, Spinal, Intervertebral Body

Device Description

The Quantum Anterior Cervical Plate System is comprised of plates and screws that are used for attachment to the anterior cervical spine (C2-C7). Plates and screws are available in a variety of sizes to suit the individual pathology and anatomic condition of the patient. The device is manufactured from titanium alloy.

Intended Use of the Device

The Quantum Anterior Cervical Plate System is intended for anterior cervical fixation (C2-C7) in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (including fracture or dislocation), spinal stenosis, deformaties or curvatures (lordosis, kyphosis, or scoliosis), tumors, pseudoarthrosis, and failed previous fusion.

Substantial Equivalence

The Quantum Anterior Cervical Plate System was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.

Performance Data

Mechanical testing indicates that the Quantum Anterior Cervical Plate is capable of performing in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2006

Quantum Orthopedics, Incorporated
c/o Mr. Jason Blain
Chief Technology Officer
2744 Loker Avenue W.
Suite 100
Carlsbad, California 92010

Re: K060491
Trade/Device Name: Quantum Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: February 21, 2006
Received: February 24, 2006

Dear Mr. Blain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060491

Device Name: Quantum Anterior Cervical Plate System

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K060491